EXHIBIT 63

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069	09/18/2006 - 10/11/2006* FEI NUMBER 3003450194

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Divya Patel, President

FIRM NAME	STREET ADDRESS
Actavis Totowa LLC	4 Taft Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Totowa, NJ 07512-1006	Pharmaceutical Packager, Labeler and Tester

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

RELEASE
REVIEWED: SAD 9/29/08
C.O. DATE

LABORATORY CONTROL SYSTEM

OBSERVATION 1

Deviations from written specifications, test procedures, and laboratory mechanisms are not justified.

Specifically, upon receipt of atypical data in the analytical laboratory, re-tests are performed without invalidating the original results. In addition, the results of re-testing are reported and original results are ignored. For example:

a) After receiving a "high dissolution value"of 117.3% drug dissolved for tablet # 5 in the dissolution testing of Benztropine Mesylate Tablets USP, 2 mg (13-week accelerated stability), no assignable cause could be identified and the analysis was re-performed with freshly prepared standard and sample solutions. The original results were ignored and the re-test results were reported.

b) "Suspect test results" in the related substance testing of Oxycodone and Acetaminophen Tablets, USP 2.5 mg / 325 mg (Batch # RBR 2467, 100 and 1000 packs, 8 week accelerated stability), were attributed to the 0.45 µm filter used to filter the sample solution. The sample chromatogram for the 1000 pack size contained unknown peaks at 4.6, 8.41, and 9.87 minutes and the sample chromatogram for the 100 pack size had a peak at the expected retention time of [redacted] (b)(4)
[redacted] of 0.6% (specification is NMT [redacted]). These results were received on 4/27/06, but no investigation was (b)(4)
initated until 5/17/06, in which the results were reported as "suspect test results" rather than "out of specification results". The filter study completed on 5/31/06 provides an explanation for unknown peaks at approximately 4.46, 8.34, and 9.52 minutes, when the filter is not pre-conditioned, but not for a peak appearing at the expected retention time of [redacted]
[redacted] (about 26.87 minutes). The original results were discarded and the repeat test results were reported. (b)(4)

c) When "comparatively lower" results were received during the related substances testing of Hydromorphone Hydrochloride Tablets USP, 8 mg, RBR 1239 at the 6-month room temperature stability test point, an investigation could find no cause to the out of trend data. The 6-month room temperature samples (both 100 and 500 packs) were re-tested, were found within the typical trend and were reported without invalidating the original results.

d) In the testing of Isradipine Capsules, USP 2.5 mg, RBR 1865 for chromatographic purity at the 12-month room temperature test point, the BP Impurity D value for both 60 count and 500 count bottles were found "significantly less

SEE REVERSE OF THIS PAGE

Kristy A. Brown, Investigator

DATE ISSUED
10/11/2006

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069	09/18/2006 - 10/11/2006* FEI NUMBER 3003450194

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Divya Patel, President

FIRM NAME	STREET ADDRESS
Actavis Totowa LLC	4 Taft Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Totowa, NJ 07512-1006	Pharmaceutical Packager, Labeler and Tester

compared to the previous stability stations." The investigation was inconclusive, the samples were re-tested and re-testing results were found to be comparable with the previous stability station results. The results of re-testing were reported without invalidating the original results.

OBSERVATION 2

The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established.

Specifically, there is no assurance that methods are appropriate for use due to repeated testing without invalidating original out of specification data obtained during method validations. For example:

a) The accuracy & precision study was repeated in the method validation of related compounds testing for Imipramine Hydrochloride Tablets, 50 mg, however the original out of specification accuracy results for Imipramine Hydrochloride and Desipramine Hydrochloride were not invalidated.

b) The linearity & range study was repeated in the method validation of dissolution testing for Phendimetrazine Tartrate Tablets USP, 35 mg, however the original out of specification results for percentage bias were not invalidated.

c) The accuracy & precision study was repeated in the method validation of related substances testing for Buspirone Hydrochloride, API, however the original out of specification accuracy results for Impurity-C were not invalidated.

d) The accuracy & precision study was repeated in the method validation of related substances testing for Benztropine Mesylate, API, however the original out of specification accuracy results for Diphenylmethane were not invalidated.

OBSERVATION 3

Verification of the suitability of the testing methods is deficient in that they are not performed under actual conditions of use.

Specifically, there is no assurance that equipment is adequately cleaned due to the deficiencies in cleaning validation studies. For example:

a) Cleaning validation was performed for the process trains of the following products without evaluating for sample

SEE REVERSE OF THIS PAGE	Kristy A. Tracy, Investigator	DATE ISSUED 10/11/2006

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069	09/18/2006 - 10/11/2006* FEI NUMBER 3003450194

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Divya Patel, President

FIRM NAME	STREET ADDRESS
Actavis Totowa LLC	4 Taft Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Totowa, NJ 07512-1006	Pharmaceutical Packager, Labeler and Tester

recovery: Carisoprodol and Aspirin Tablets USP 200 mg/325 mg, Carisoprodol Tablets USP 350 mg, Phentermine Hydrochloride Capsules USP 30 mg and 37.5 mg CIV, and Ursodiol Capsules USP 300 mg.

b) Recovery studies were performed by applying a known amount of active pharmaceutical ingredient directly to a swab instead of applying the active to a coupon or template to replicate the equipment surface from which the active should have been swabbed. Cleaning validation was performed in this manner for the process trains of the following products: Buspirone Hydrochloride Tablets USP 5mg, 10 mg and 15 mg, Pentazocine Hydrochloride and Acetaminophen Tablets 25 mg and 650 mg CIV and Tizanidine HCl Tablets 2 mg and 4 mg.

c) Cleaning Validation studies do not indicate whether or not a cleaning agent was used when cleaning the equipment process train. The current standard operating procedures DOI # PRD-186: [redacted] (b)(4)
Effective Date: 10/11/99, and DOI # PRD-224: [redacted] (b)(4)
Procedure, Effective Date: 4/19/05 indicate that equipment could be cleaned "[redacted] (b)(4)
". In addition, there are no studies to show the cleaning agent is effectively removed from equipment during the cleaning process.

* DATES OF INSPECTION:
09/18/2006(Mon), 09/19/2006(Tue), 09/20/2006(Wed), 09/26/2006(Tue), 09/27/2006(Wed), 09/28/2006(Thu), 10/02/2006(Mon), 10/04/2006(Wed), 10/11/2006(Wed)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Kristy A. Zielny, Investigator

SEE REVERSE OF THIS PAGE	Kristy A. Zielny, Investigator	DATE ISSUED 10/11/2006